

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS

)
) Judge Patti B. Saris
THIS DOCUMENT RELATES TO:)
)
The City of New York v. Abbott Labs., et al.)
(S.D.N.Y. No. 04-CV-06054))
)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-05126))
)
and other cases listed on the following page)

**SEPARATE REPLY MEMORANDUM OF MERCK & CO., INC.
IN SUPPORT OF ITS MOTION TO DISMISS**

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May 11, 2006

THIS DOCUMENT RELATES TO:)	<i>County of Herkimer v. Abbott Labs, et al.</i>)
)	(N.D.N.Y. No. 05-CV-00415))
<i>The City of New York v. Abbott Labs., et al.</i>)	<i>County of Oneida v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 04-CV-06054))	(N.D.N.Y. No. 05-CV-00489))
<i>County of Suffolk v. Abbott Labs., et al.</i>)	<i>County of Fulton v. Abbott Labs, et al.</i>)
(E.D.N.Y. No. 03-CV-229))	(N.D.N.Y. No. 05-CV-00519))
<i>County of Westchester v. Abbott Labs., et al.</i>)	<i>County of St. Lawrence v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 03-CV-6178))	(N.D.N.Y. No. 05-CV-00479))
<i>County of Rockland v. Abbott Labs., et al.</i>)	<i>County of Jefferson v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 03-CV-7055))	(N.D.N.Y. No. 05-CV-00715))
<i>County of Putnam v. Abbott Labs, et al.</i>)	<i>County of Lewis v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 05-CV-04740))	(N.D.N.Y. No. 05-CV-00839))
<i>County of Dutchess v. Abbott Labs, et al.</i>)	<i>County of Chautauqua v. Abbott Labs, et al.</i>)
(S.D.N.Y. No. 05-CV-06458))	(W.D.N.Y. No. 05-CV-06204))
<i>County of Washington v. Abbott Labs, et al.</i>)	<i>County of Allegany v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00408))	(W.D.N.Y. No. 05-CV-06231))
<i>County of Rensselaer v. Abbott Labs, et al.</i>)	<i>County of Cattaraugus v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00422))	(W.D.N.Y. No. 05-CV-06242))
<i>County of Albany v. Abbott Labs, et al.</i>)	<i>County of Genesee v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00425))	(W.D.N.Y. No. 05-CV-06206))
<i>County of Warren v. Abbott Labs, et al.</i>)	<i>County of Wayne v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00468))	(W.D.N.Y. No. 05-CV-06138))
<i>County of Greene v. Abbott Labs, et al.</i>)	<i>County of Monroe v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00474))	(W.D.N.Y. No. 05-CV-06148))
<i>County of Saratoga v. Abbott Labs, et al.</i>)	<i>County of Yates v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00478))	(W.D.N.Y. No. 05-CV-06172))
<i>County of Columbia v. Abbott Labs, et al.</i>)	<i>County of Niagara v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00867))	(W.D.N.Y. No. 05-CV-06296))
<i>Essex County v. Abbott Labs, et al.</i>)	<i>County of Seneca v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00878))	(W.D.N.Y. No. 05-CV-06370))
<i>County of Chenango v. Abbott Labs, et al.</i>)	<i>County of Orleans v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00354))	(W.D.N.Y. No. 05-CV-06371))
<i>County of Broome v. Abbott Labs, et al.</i>)	<i>County of Ontario v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00456))	(W.D.N.Y. No. 05-CV-06373))
<i>County of Onondaga v. Abbott Labs, et al.</i>)	<i>County of Schuyler v. Abbott Labs, et al.</i>)
(N.D.N.Y. No. 05-CV-00088))	(W.D.N.Y. No. 05-CV-06387))
<i>County of Tompkins v. Abbott Labs, et al.</i>)	<i>County of Chemung v. Abbott Lab, et al.</i>)
(N.D.N.Y. No. 05-CV-00397))	(W.D.N.Y. No. 05-CV-06744))
<i>County of Cayuga v. Abbott Labs, et al.</i>))
(N.D.N.Y. No. 05-CV-00423)))
<i>County of Madison v. Abbott Labs, et al.</i>)	and)
(N.D.N.Y. No. 05-CV-00714))	<i>County of Nassau v. Abbott Labs, et al.</i>)
<i>County of Cortland v. Abbott Labs, et al.</i>)	(E.D.N.Y. No. 04-CV-05126))
(N.D.N.Y. No. 05-CV-00881)))

Defendant Merck & Co., Inc. (“Merck”) joins the Defendants’ joint reply memorandum and submits this separate reply memorandum in support of its motion to dismiss both the Consolidated Complaint and the Nassau Complaint as to Merck.¹

Discussion

1. Plaintiffs’ allegations that transactions occurred at a price below AWP do not satisfy Rule 9(b) or state a claim for AWP fraud.

Plaintiffs acknowledge that this Court’s prior orders require that allegations of AWP fraud be made with particularity as to each defendant and that they be made as to specific drugs. Opp. at 2. Where, as with Merck, Plaintiffs rely on assertions of the existence of a spread with no specific conduct allegations, Plaintiffs must also demonstrate a “good-faith basis for the calculation.” *Id.*

Plaintiffs allege no specific conduct by Merck. Instead, they rely on the assertion that the AWP for *all* Merck drugs reimbursed by every County were fraudulent, because AWP for certain formulations of *two* Merck drugs “exceeded transaction prices by greater than 40% in 2000.” Opp. at 3 (citing Ex. B-21). This allegation does not suffice even for those two Merck drugs. Plaintiffs acknowledge that AWP typically exceeds WAC (or a “‘WAC equivalent’ such as direct price or list price”) by 20% to 25%, and expressly deny that the 20%-25% mark-up constitutes the basis for their fraud claims. Consol. Compl. ¶¶ 6-8. Plaintiffs do not mention Merck in their Exhibit F, which purports to assert WAC to AWP spreads for certain other defendants’ products. *See id.* ¶ 8 & Ex. F.

Instead, the Counties mistakenly seem to believe they can satisfy Rule 9(b) and the standard set by the Court’s prior rulings by alleging the existence of *any* price that differs from

¹ With respect to Suffolk County, Plaintiffs now assert that this Court did not dismiss all of Suffolk County’s claims against Merck. Plaintiffs’ Opposition to Separate Memorandum of Merck & Co., (“Opp.”), at 1. But Plaintiffs stipulated—and this Court incorporated into its order—that Suffolk County does not join in the Consolidated Complaint with respect to *any* claims against Merck. *See* Case Management Order 21, at 3 (entered Feb. 2, 2006).

AWP by more than 25%. But the Court requires a good faith showing of a “basis for calculating a spread between the published AWP and *the actual average price at which the drug is sold by wholesalers.*” *Suffolk III*, at 1 (D. Mass. Apr. 8, 2005). The “available” prices that the Counties compare to Merck’s alleged AWP’s do not even purport to be actual average prices. Consol. Comp. ¶ 124. Just as extrapolating a spread by application of a single formula to all drugs did not suffice to state a claim for fraud, neither does calculating a “spread” based on a single price point from a single source.

Apart from failing to comply with the Court’s instruction to plead “particular facts” as to “particular drugs,” *see* Clarification Order (entered Nov. 23, 2004), the two Merck drugs in Exhibit B-21 are described as “vials” (*i.e.*, for intravenous use) and Plaintiffs have conceded that such physician-administered drugs were not reimbursed based on AWP in 2000, *see* Pls.’ Opp. to Def. Amgen’s Ind. Mem., at 5. The prices allegedly paid for those two drugs are simply irrelevant to the vast majority of Merck drugs that Plaintiffs list in Exhibit A, which are tablets or capsules that are sold, administered, and reimbursed on a different basis.

2. Plaintiffs’ allegations relating to nominal prices cannot support Best Price or AWP claims.

Plaintiffs’ Opposition relies heavily on allegations that Merck failed to include in its calculation of Best Price certain “nominal prices” charged to hospitals for three drugs. But Plaintiffs fail to address the statutory and Rebate Agreement provisions that explicitly provide that such prices are *not* to be included in that calculation. *See* 42 U.S.C. § 1396r-8(c)(1)(C)(ii) (“The term ‘best price’ . . . shall not take into account prices that are merely nominal in amount.”); Rebate Agreement at I(d) (same).² Merck invited the Counties to explain how

² *See* Medicaid Drug Rebate Program Release No. 14, at 2 (“Please remember that any prices which are nominal in amount, *that is, less than 10% of the AMP* . . . are excluded from the best price calculation. Therefore, if any arrangement results in prices which are nominal, *those sales*

allegations of conduct *consistent* with the applicable law can state a fraud claim. *See* Merck Mem. at 4. In response, the Counties cite a Wall Street Journal article, reporting on investigations into whether Merck sold certain drugs to hospitals at discounts of more than 90% (*i.e.*, at nominal prices) and did not account for those sales in its reported Best Price. The article itself notes that “the law says that medicines sold at a discount of 90% or more don’t have to be disclosed to the government or included in the best-price calculation.” Barbara Martinez, *Deep Discounts By Drug Firms Draw Scrutiny*, Wall St. J., Apr. 28, 2005, at B1. That Merck’s sales at the nominal prices identified in the article were alleged (although never adjudicated) to have been inconsistent with other laws provides no support for claims that those prices should have been included in Merck’s Best Price reporting despite the clear direction of the law to the contrary.

Even more far-fetched is the Counties’ contention that Merck failed to account for nominal prices in its “calculations of average wholesale prices.” Opp. at 5. This assertion contradicts the Counties’ acknowledgement that “it has been established that the AWP is based on the WAC or direct prices, to which the publisher applies a standard 20 or 25% markup.” Opp. at 4 n.5. In any event, the Counties identify no legal authority to suggest that AWP should take into account prices statutorily excluded from price calculations under Medicaid.³ The Counties cannot plead fraud by simply alleging that certain numbers differ from one another without providing any basis in law that one should bear any relation to the other.

and prices do not affect best price and must be excluded by the manufacturer” (emphasis added)) (Attachment 2 to United States’ Reply Brief As Amicus Curiae (filed Apr. 23, 2004)).

³ Sales to hospitals at nominal prices are excluded not only from Best Price, but also from the calculation of Average Manufacturer Price, because such sales are not to the retail pharmacy class of trade. *See* 42 U.S.C. § 1396r-8(k)(1).

Conclusion

For the reasons stated above and in Merck's previous separate memorandum and the Joint Memorandum, the Consolidated Complaint and the Nassau Complaint should be dismissed as to Merck.

Dated: May 11, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on May 11, 2006, I caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Robert B. Funkhouser

Robert B. Funkhouser